

### ***REMARKS***

Claims 1 through 7 continue to be in the case.

New claims 8 through 14 are being submitted.

New claim 8 is based on the language of claim 1.

New claim 9 is based on the language of claim 2.

New claim 10 is based on the language of claim 3.

New claim 11 is based on the language of claim 4.

New claim 12 is based on the language of claim 5.

New claim 13 is based on the language of claim 6.

New claim 14 is based on the language of claim 7.

New claim 15 is based on the language of claim 8.

New claim 16 is based on the language of claim 9.

New claim 17 is based on the language of claim 11.

New claim 18 is based on the language of claim 14.

New claim 19 is based on the language of the specification, page 14, lines 11 through 15..

New claim 20 is based on the language of claims 8 and 13.

New claim 21 is based on the language of claim 10.

New claim 22 is based on the language of the specification, page 14, lines 16 through 19..

New claim 23 is based on claims 9, 11, and 20.

New claim 24 is based on the language of claim 23.

New claim 25 is based on claim 5, the specification, page 14, lines 3 to 5,.

New claim 26 is based on the specification, page 14, lines 16 through 19, page 15, lines 1 through 5.

***The Office Action refers to the Specification.***

1. The disclosure stands objected to because of the following informalities: It is the Examiner's position that Applicant has evoked 35 U.S.C. 112, 6<sup>th</sup> paragraph, means-plus-function language to define Applicant's invention. Therefore, the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets for the structure, materials, or acts corresponding to the means- (or step-) plus-function claim element in compliance with 35 U.S.C. 11, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)..." (Also see MPEP 2181 [Rev. 1, February 2000]). Appropriate correction is required.

The applicant recites in claim 1 : “means of immobilization (10, 12, 26)”. These means of immobilization are set forth in the specification, page 13, line 15 as bayonet device 10, 12 with slots 10 and in the specification, page 14, line 1, as a tapping 26.

***The Office Action refers to Claim Objections.***

2. Claims 1-7 stand objected to because of the following informalities: It is the Examiner's position that Applicant has evoked 35 U. S. C. 112, 6d' paragraph, means-plus-function language to define Applicant's invention. Therefore, the Examiner has objected to the claims for the reasons set forth above in the objection to the specification . Appropriate correction is required.

The supporting elements in the specification of the means language are set forth above. Newly introduced claim 8 avoids the “means” language present in claim 1.

3. Claim 3 stands objected to because of the following informalities: Claim 3 recites the limitation "the said nesting organ" in lines 4-5 of the claim. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

The Applicant corrects claim 3 in the present amendment.

***The Office Action refers to Claim Rejections - 35 USC § 112.***

4. Claims 1-7 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Claims 1 through 7 have been presented by the applicant from overseas and have experienced some corrections. New claims 8 through 14 are being submitted, which are similar to claims 1 through 7 in many respects, but which are better adapted to the North American practice. New Claims 15 through 19 refer to a screwing arrangement (26). New claims 20 through 22 refer to a bayonet device (10, 12). New claim 23 refers to a kit of the version with the screwing arrangement. New claims 24 through 26 refer to a method involving the screwing arrangement (26).

***The Office Action refers to Claim Rejections - 35 USC § 102.***

5. Claims 1, 2, 5 and 6 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,344,435 to Aubin. Aubin discloses a tube 14, skin collar 18, intravisceral collar 16 and means of immobilization (screw threading). See Figures 1-5.

The claims under consideration require a presence of a first part (2) of the transparietal tube and of a second part (4) of the transparietal tube. The first part (2) of the parietal tube and the second part (4) of the parietal tube are important as they allow for a length adjustment of the transparietal tube. The central cylindrical portion 14 (reference Aubin, column 4, line 36) is fixed in length and is not adjustable in length. Thus the reference Aubin fails to teach or to suggest the first part (2) of the transparietal tube and the second part of the transparietal tube.

The present invention allows the inosculation of a hollow organ to the skin of a patient. In particular, the technique of the present invention is used for organs located in the abdomen. In other words, the present invention technique makes it possible to access to internal cavity of the organ from an aperture in the skin of the patient. Thus, by << press on>> of

the surface of the organ against the skin, there exists a continuous aperture from the exterior to the interior of the organ.

The present invention device makes it possible to access permanently the inside of an organ. The present invention device has a length that can vary by screwing. Therefore, the present invention device can be easily, immediately, and permanently adapted to any variation of the thickness of the abdominal wall and the organ wall for a patient.

Claim 2 of the present application requires that the second part (4) of the transparietal tube to be specially constructed for being gripped by the pusher (16). The reference Aubin fails to teach that any part of the central cylindrical portion 14 (reference Aubin, column 4, line 36) be gripped by any pusher. Thus claim 2 defines the present invention patentably over the reference Aubin.

Claim 5 requires that the transparietal tube is telescopic and comprises a first part (2) and a second part (4). In contrast, the central cylindrical portion 14 (reference Aubin, column 4, line 36) is clearly not telescopic and is a single part.

Thus the reference Aubin fails to teach the features of claim 5 of the present application.

Claim 6 requires that the second part (4) of the transparietal tube be connected to the first part (2) of the transparietal tube by a screw connection (26). Since the central cylindrical portion 14 (reference Aubin, column 4, line 36) is a single piece, the screw connection (26) of the present claim 6 is clearly absent from the reference Aubin. Thus the reference Aubin does not anticipate claim 6.

According to the reference Aubin, US Patent 4 344 435, the device used for inosculation of a hollow organ needs incision for insertion in the cavity. An incision is a surgical act, that is the resolved by the invention. Contrary to the present invention, the length of the central cylindrical portion 14 of the reference Aubin cannot be adjusted by screwing to fit the thickness of the abdominal wall.

The present invention allows to position a device permitting permanently the inosculation of a hollow organ to the skin. The present invention device can be installed and immediately adapted to the thickness of the wall involved, for any patient. A variation in the distance between the two collars (intravisceral and skin collars) is possible because the practitioner can screw the two parts of the tube, with no adverse effect on the

patient. So the present invention device can be easily adapted to any variation of the thickness of the wall for any patient.

The device taught in the reference Aubin, US Patent 4,344,435 includes a central cylindrical portion 14, which cannot be adjusted in its length. In contrast, the present invention device is permanently adaptable to any variation of the thickness of the abdominal wall and the respective organ wall.

***The Office Action refers to Claim Rejections - 35 USC § 103.***

6. Claim 7 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Aubin.

Aubin discloses the claimed invention as shown above. Aubin, however, does not disclose expressly a bayonet fitting.

Applicant respectfully disagrees. The reference Aubin does not only fail to teach a bayonet device, but other things also such as a first part (2) of a transparietal tube and a second part (4) of the transparietal tube.

The Office Action continues that at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to substitute a bayonet fitting for a screw fitting because Applicant has not disclosed that a



bayonet fitting provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the screw fitting of Aubin because a screw fitting and bayonet fitting are both well known and used interchangeably in the art for mechanical connectors. Therefore, it would have been an obvious matter of design choice to modify Aubin to obtain the invention as specified in claim 7.

Applicant respectfully disagrees. The reference Aubin clearly fails to teach a screw connection (26) between a first part (2) of a transparietal tube and a second part (4) of a transparietal tube. Thus, the screw connection (26) between a first part (2) of a transparietal tube and a second part (4) of a transparietal tube of claim 6 distinguishes the present invention from the teaching of the reference Aubin.

7. Claims 3 and 4 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Aubin in view of U. S. Patent No. 5,391,156 to Hildwein et al. (hereinafter "Hildwein"). Aubin shows the claimed invention as shown above except for a noncircular opening and a pusher. Hildwein discloses a portal having a noncircular opening 142 and pusher 174. See Figure 28. It would have been obvious to one of ordinary skill in the art to modify the invention of Aubin with a noncircular opening and corresponding pusher, as suggested by Hildwein, to maintain a specific orientation between the pusher and the opening.

Applicant respectfully traverses the reference Aubin as above set forth.

The element 174 of the Hildwein et al. reference is not a pusher, but an obturator. The reference Hildwein et al. further fails to refer to the obturator in connection with Fig. 28. The reference Hildwein et al. says in connection with Figs. 23 and 24 that 'The obturator 174 is oval in cross section or has a variable geometry to allow the trocar tube 140 to be received in the intercostals spacing of the adjacent ribs 82 in the body wall 80.'

Therefore, the purpose of the oval cross section is to fit the obturator 174 between two adjacent ribs more easily, but not to make a fitting to the shape of a pusher (16). In fact, no the reference Hildwein et al. fails to teach any pusher.

Furthermore, an obturator 174 of oval cross section would not be suitable to substitute the first part (2) of the transparietal tube or the second part (4) of the transparietal tube, since these parts are joined by a screw connection (26), which screw connection (26) can exist only with a cylindrical symmetry and not with an oval cross section.

Applicant urges that the replacement of the cylindrically shaped central cylindrical portion 14 (reference Aubin, column 4, line 36) by a central oval portion would result in a non operating device, since the threads 46 on a double threaded spacer 48 located between the threaded cap 44 and a cylindrical portion of the spool-shaped member 12 would not engage a spool-shaped member of oval cross-section.

In summary, substitution of the first part (2) of the transparietal tube or of the second part (4) of the transparietal tube with an oval obturator 174 of the reference of Hildwein et al. would result in a non-operating device, since the oval obturator would not allow a screw connection (26) based on cylindrical symmetry.

According to the reference Hildwein et al., US Patent 5 391 156 there is taught a device of a trocar used to carry out a thoracoscopy or a laparoscopy. In no case, the trocar goes inside an organ. This device of the reference Hildwein et al. only permits the insertion of an instrument in the thoracic or abdominal cavity.

According to another embodiment, the device of the reference Hildwein et al. is flexible, so that the instrument can be moved in several directions in the cavity (figures 8, 9, 16a, 16b). According to another

configuration, shown in figures 17 to 22, the tube inserted through the thoracic wall is fastened by an inside and an outside collar on the wall. Contrary to the invention, the distance between the two collars of the Hildwein et al. reference cannot be modified.

The reference Hildwein et al. teaches a device for a different technical field: The Hildwein et al. device is limited to go inside a thoracic or abdominal cavity. This is completely different from going into a hollow organ disposed in the thoracic cavity or disposed in the abdominal cavity.

Reconsideration of all outstanding rejections is respectfully requested. All claims as presently submitted are deemed to be in form for allowance and an early notice of allowance is earnestly solicited.

Respectfully submitted,

Thierry Scheye

By:



Horst M. Kasper, his attorney  
13 Forest Drive, Warren, N.J. 07059  
Tel.: (908)526-1717; Reg. No. 28559  
Attorney's Docket No.: CHA216A2

\*%AMEND(CHA216A2)August 16, 2004(mm/am/mb/rep